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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/665,871 | 09/18/2003 | Jean-Pascal Zambaux | ATMI-657 | 6762 |
| 25559 | 7590 | 09/08/2005 | EXAMINER | |
| ATMI, INC. 7 COMMERCE DRIVE DANBURY, CT 06810 | | | BIANCO, PATRICIA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3761 | |

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|--|---|---|--|
| <p align="center">Office Action Summary</p> | <p>Application No.</p> <p>10/665,871</p> | <p>Applicant(s)</p> <p>ZAMBAUX, JEAN-PASCAL</p> | |
| | <p>Examiner</p> <p>Patricia M. Bianco</p> | <p>Art Unit</p> <p>3761</p> | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6,9-15,17,19,20,22-34,37,38 and 40-45 is/are rejected.
- 7) ☒ Claim(s) 3,4,7,8,16,18,21,35,36,39,46 and 47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

The original claims presented were numbered 1-49, however, claims 8 & 9 do not exist in the papers filed by applicant.

Originally filed/misnumbered claims 10-49 been renumbered **8-47**.

As a result, the number of claims pending is **1-47**.

Election/Restrictions

The reply Applicant filed with arguments traversing the restriction in the on 8/30/05 is acknowledged. The traversal is on the ground(s) that the two groups are not independent and distinct. The claims and restriction requirement have been reviewed and applicant's arguments are persuasive. The requirement has been withdrawn. All the claims have been examined on the merits.

Claim Rejections - 35 USC § 112

Claim 8 (original claim 10) is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention. Claim 8 is dependent from "claim 9" which was not presented in the application. Therefore, it is unclear which of the preceding claims applicant intended claim 8 to be dependent upon and the meets and bounds of the claim cannot be determined.

Claim 1 recites the limitation "***transferring the fluids***" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the kit as claimed in claims 46-49 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

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of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 9-11, 17, 19, 20, 22-30, 37, 38, & 40-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Walter (Re. 25,129). Walter discloses an apparatus having multiple containers for holding a medical fluid, such as blood or other biological products, and then dispensing the fluid from the containers. The flexible bag container (10) has a connector that comprises a needle cannula (16) surrounded by a tubular sheath/diaphragm (17). The connector is said to be sealed for protection of the cannula and outlet from bacterial contamination. It is inherent that air (i.e. gas) will be within the sheath and remain there until the seal is broken and that the air/gas would be sterile, or at least about more than 95%. As shown in figure 7, the connector may be further connected to a second connector^{46/47}, which is in turn connected to a second container (42).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 12-15, 31-34, 44, & 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walter (Re. 25,129). Walter discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the air/gas has a pressure greater than about 1.05 atm or that the membrane has a thickness of less than about 15 microns to about 200 microns. It would have been obvious to one having ordinary skill in the art at the time the invention was made to choose a pressure for the air/gas within the sheath to be greater than about 1.05 atm or to make the membrane of a thickness of less than about 15 microns to about 200 microns, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). With respect to claims 44 & 45, it is well known that medical devices are shipped and received in a container or kit, and the container will have indicia or lettering on said container to identify what is inside. Further, it is generally well known in the art to include instructions for use of the product. At the time of the invention, it would have been obvious to one having ordinary skill in the art to have placed the assembly in a kit with instructions.

Allowable Subject Matter

Claims 3, 4, 7, 8, 16, 18, 21, 35, 36, 39, 46, & 47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

With respect to claims 4, 7, 16, 35, & 46, the subject matter of the independent claims could either not be found or was not suggested in the prior art of record. The subject matter not found was the membrane having a slit or cut that does not penetrate completely through the membrane in combination with the other elements (or steps) in the claims.

With respect to claims 3, 18, 36, & 47, the subject matter of the independent claims could either not be found or was not suggested in the prior art of record. The subject matter not found was the apparatus having a latch coupled between the container and the hollow connector in combination with the other elements (or steps) in the claims.

With respect to claims 21 & 39, the subject matter of the independent claims could either not be found or was not suggested in the prior art of record. The subject matter not found was the connector being configured to attach to the container via a threaded connection in combination with the other elements (or steps) in the claims.

Claim 8 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. The subject matter of the independent claims could either not be found or was not suggested in the prior art of record. The subject matter not found was the membrane having a slit or cut that does not penetrate completely through the membrane in combination with the other elements (or steps) in the claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Olson et al. (5,122,129) discloses a coupler device having a lever and the connector has membrane surrounding a needle to collect fluid drips.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M. Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 3rd, 2005

Patricia M Bianco
Primary Examiner
Art Unit 3761


PATRICIA BIANCO
PRIMARY EXAMINER